REMARKS

This application as originally filed contained claims 1-22. Claims 1 and 20 are hereby amended, and Claim 23 is new. Applicants respectfully submit that the present amendments provide no new matter, and are fully supported by the as-filed specification; moreover, the amendments to claims 1 and 20 are made to comply with the restriction requirement, and are not narrowing, nor made for any reason related to patentability. Applicants expressly reserve the right to prosecute restricted material in another application. No other claims are hereby amended, newly added nor cancelled in/by this paper.

Claim 20 is rejected and claims 1-3, 7-11, 14, 16-19, 21, and 22 are objected to. Claims 4-6, 12, 13, and 15 were withdrawn from consideration. Applicants respectfully request reconsideration and allowance of all pending claims.

Restriction Election Requirements

Applicants respectfully note the combination of groups VI, VII, VIII, XIV, XV and XVI with elected group V are under examination. Nevertheless, Applicants maintain their traverse of the election requirement as set forth in the previous response to Office Action.

Applicants also note that no objectionable or restricted matter remains explicitly within the currently pending non-withdrawn claims; i.e., claims 1-3, 7-11, 14, and 16-23. The objections thereto are respectfully requested to be withdrawn.

Specification

Applicants note that the abstract of the disclosure appeared in the official copy of the application sent by WIPO to the USPTO, and was also present in the US publication version of the current application. The abstract is/was in this case as required. However, as further

required by the Office Action, Applicants have re-submitted herewith an additional copy of the abstract on a separate sheet. This objection can respectfully be withdrawn.

Claim Rejections – 35 USC § 112

Claim 20 is rejected under 35 USC § 112, first paragraph, as purportedly failing to comply with the enablement requirement. The Office Action alleges that the claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically the Office Action alleges that the present specification does not enable "utility for treating every known cancer." (Office Action (OA), page 4, lines 7-8.) The Office Action further alleges this would require undue experimentation per the different factors cited in In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). Applicants respectfully submit that the Claim 20 is more than sufficiently enabled under 35 USC 112 and therefore request withdrawal of this rejection.

As the Office Action acknowledges (OA, pg. 3, lls 15-16), the specification teaches the inhibitory effects of the instant compounds for at least two cell lines: Jurkat, which is a leukemia derived line, and GLC-4, which is a lung cancer line. This experimental evidence represents at least two concrete, different cancers, which provides support for a generic claim to cancer.

Of the eleven different compounds tested in the Jurkat line, all showed activity in the low micromolar to nanomolar range (see Table 1, p. 12, col. 1 of the publication version of the application, referred to in Example 30, para. [0068], p. 11, col. 2). Of the fourteen compounds tested in the GLC-4 line, all compounds showed activity in the low micromolar to nanomolar range. Thus, Applicants have demonstrated that a representative number of the compounds of the present developments have activity in these two diverse cancers. Applicants submit that this, in and of itself, is sufficient to enable claim 20.

Moreover, the specification, in para. [0025] (p. 5, col. 2 of the publication version of the application), teaches that compounds of Formula I are intercalators, i.e. compounds that intercalate DNA. Intercalators are a large class of compounds that are thought to have their

effect in cancer by disrupting the synthesis of DNA in rapidly dividing (i.e. cancer) cells and thus have broad therapeutic applicability in many cancers. This is evidenced by the numerous different intercalators approved for clinical use in diverse cancers. In fact the National Cancer Institute defines intercalators as follows: "Intercalator In biochemistry, a type of molecule that binds to DNA and inserts itself into the DNA structure. Some intercalators are used as treatments for cancer". See Exhibit A (NCI dictionary definition), attached hereto (and see http://www.cancer.gov/dictionary/?CdrID=318816).

The results in Example 30 (para [0068], p. 11, col. 2 of the publication version of the application) show the compounds of Formula I are active for cancer treatment. Thus, Applicants submit as a factual matter that the tests shown in Example 30, when read together with the statement that the compounds are intercalators, satsifies the enablement requirement for "cancer".

One particularly relevant case on point is In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) which was discussed much more recently in view of the new utility guidelines, but actually is a section 112 first paragraph case. The Brana claims were directed to anti-tumor compositions which had been tested against a minimal number of cancer cell lines, in vitro mouse lines not unlike those in issue here. In Brana, the antitumor compositions in issue had been tested against the P388 and L1210 cell lines **both of which were lymphocytic leukemia lines**. The examiner in that case had rejected on 35 USC 112 grounds, just as were the rejections in this case. Ultimately, the Federal Circuit found that the two lines of Brana were sufficient to enable the utility of the claimed anti-tumor compositions. The situation in the present case has positive tests against the two cell lines from two completely different types of cancers, the Jurkat (leukemia) and the GLC-4 lines (lung cancer), which are sufficient to enable utility of the current method claim, claim 20. Applicants respectfully submit, that proving utility against "every known cancer" is simply not necessary under Brana or by any other legal authority including In re Wands.

More generally, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance

with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); In re Langer, 183 USPQ 288 (CCPA 1974). In other words, if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. In re Brana, 51 F.3d at 1566, 34 USPQ2d at 1441 (Fed. Cir. 1995); MPEP 2164.02. Given that the Federal Circuit indicated that the examiner in that case did not make a *prima facie* case of lack of enablement, Applicants submit that a *prima facie* case of lack of enablement has not been made in this case.

However, the Office Action alleges that there is no teaching or guidance in the specification or the prior art showing that "the instant compounds" that work in "these two cell lines" also will have "therapeutic utility for treating every known cancer in the art." (OA, pg. 3, lls 17-21.) Furthermore, the Office Action alleges that "[t]here is no teaching or guidance regarding the mechanism of action of the instant compounds" (OA, pg 3, lls 21-22) and that "[t]here are no working examples present showing inhibitory effect of [the] instant compounds in known in vitro cell lines of every known cancer in the art." (OA, pg 4, lines 1-3.) The Office Action finally alleges in conclusion that "it would require undue experimentation to demonstrate efficacy of instant compounds in known in vitro cell lines of every known cancer in the art and hence their utility for treating every known cancer." (OA, page 4, lines 5-8, emphasis added.) Applicants respectfully submit that these issues, which Applicants believes are not completely accurate, still do not amount to a prima facie case of lack of enablement (e.g., the specification discloses that the compounds are intercalators and the Applicant is not aware of laws that indicate that every specific embodiment of a claim need to be proven).

The Applicants respectfully submit that the Office Action is not using the correct test of enablement by requiring a showing that all compounds have efficacy in all cell lines. This is an extreme interpretation of enablement that is not supported by law. **In the as-filed specification.**

Applicants have demonstrated anticancer activity for a representative number of compounds for several cell lines derived from diverse cancers and indicated the mechanism of action of these compounds makes these compounds useful for treating cancer in general. As a result, Applicants submit that Claim 20 fully complies with the enablement requirement.

Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

Applicants note that all rejections are obviated or traversed and respectfully request that they thus be withdrawn. A timely Notice of Allowance is thus requested to be issued in this case. Applicants believe that other than the single extra claim fee, no fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this a request therefore and authorization to charge Deposit Account No. 02-2093 as necessary. The Examiner is requested to please contact the undersigned attorney if there are any questions.

Respectfully Submitted,

Date: September 29, 2009

/peterbscull/
Peter B. Scull
Reg. No. 37,932
Berenbaum Weinshienk PC
370 Seventeenth St., Suite 4800
Denver, CO 80202
+1 303 825 0800